Draft Meeting Summary
Cardiac Services Advisory Committee
First Meeting, November 5, 2014
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215

Work Group Member Attendees:

Thomas Aversano, M.D. (by phone)
Jaime Brown, M.D. (by phone)
Nancy Bruce, R.N., M.B.A
Jesus Cepero, Ph.D. (by phone)
John Conte, M.D. (by phone)
Blair Eig, M.D. (by phone)
Keith Horvath, M.D. (by phone)
Paul Massimiamo, M.D. (by phone)
Jerry Segal, M.D.
Stuart Seides, M.D.
Bill Thomas, M.D.
Mauro Moscucci, M.D.
Steven Hearn, M.D.
James Gammie, M.D.
Christopher Haas, D.O.
Josemartin Ilao
Lisa Myers, R.N., M.S.
Juan Sanchez, M.D.
Sharon Sanders, R.N., M.B.A. (by phone)
Stafford Warren, M.D.
David Zimrin, M.D.

MHCC Staff Attendees:

Ben Steffen, Executive Director
Paul Parker, Director for the Center for Health Care Facilities and Planning
Suellen Wideman, Assistant Attorney General
Eileen Fleck, Chief, Acute Care Policy and Planning

Other Attendees:

Rebecca Canino, Johns Hopkins Bayview
Patricia Cameron, MedStar Health
Barbara Courtney, Shady Grove Adventist Hospital
Mike Gibson, Prince George's Hospital Center
Elisabeth H., Johns Hopkins
Tamara McDuffie, Sinai Hospital
Gail Shults, Shady Grove Adventist Hospital
Matt Voss, St. Agnes Hospital
Regina Woods, UM St. Joseph Medical Center
Vanessa Wyrick, UM St. Joseph Medical Center

Introductions

The meeting convened at approximately 6:10pm. Ben Steffen introduced himself and thanked everyone for attending. He asked for members calling in to the meeting to introduce themselves and then everyone present. Ben Steffen noted that new regulations were developed that became effective in August 2014 and established a new structure for oversight of cardiac services. He briefly reviewed the agenda for the meeting.

Discussion of Proposed External Peer Review Requirements

Eileen Fleck explained that the proposal developed by MHCC staff was based on the current regulations, national guidelines, and internal peer review forms provided by hospitals. She also noted that she spoke to a few individuals from various hospitals in order to identify key issues for discussion by the CSAC. She noted that the first external review required for hospitals would only be subject to the requirements currently included in the regulations, but MHCC staff is hoping to have formal regulations adopted before the next external peer review cycle. She explained that would likely require meeting again in January and proposed regulations would need be ready in April 2015. She then led the group through the discussion guide developed by MHCC staff.

Ms. Fleck described the requirements for external review included in the current regulations, including the definition of external review. She noted that the regulations eliminate some opportunities for bias, but staff proposes that patient, physician, and hospital names be blinded.

Dr. Blair Eig, asked whether the five percent of cases that must be externally reviewed refers to a percentage of practitioner cases or cases from an institution. Ms. Fleck responded that the requirement is for an institution, but she also noted that there is a requirement for reviewing a minimum number of an interventionalist's cases annually.

Dr. Bill Thomas asked Ms. Fleck to distinguish between regulations and staff recommendations. Ms. Fleck explained that a few basic requirements exist in the current regulations, and MHCC staff has concluded that additional guidance is needed to insure the external reviews are consistent in rigor, and reviewers make similar judgments.

Dr. Thomas commented that there are other procedures where MHCC does not apply the same type of approach. He also asked whether staff had thought about what happens next in other service lines, such as oncology or organ transplants, which have national review bodies, but not similar State oversight. Mr. Steffen responded by noting that specific events (inappropriate use of stents by two Maryland physicians) prompted the requirement for external review of PCI cases, and he does not anticipate an expansion to other services.

Dr. Steve Hearn asked who was responsible for the cost of external reviews. Staff responded that hospitals are responsible for covering the cost. Dr. Hearn noted that his hospital, Peninsula Regional Medical Center, has been under a Corporate Integrity Agreement (CIA) with the federal government for five years, and it is very expensive and time consuming. Cases are blinded and sent out. He commented that cardiology has been unfairly singled out based on the actions of a single operator. Mr. Steffen noted that purpose is not to debate those issues again. The legislature directed MHCC to take the approach that it is undertaking. Dr. Hearn acknowledged that he understood Mr. Steffen's point.

Dr. Stuart Seides commented that looking at angiograms is reasonable, but a full review of cases is very expensive. He also noted that blinding of cases is almost impossible, even though it's ideal. The source of films will still be identifiable in a small state. He also noted that precluding review by hospitals in the same systems results in too few doctors to conduct reviews. He also question whether all of the proposed work is needed to solve the problem that MHCC seeks to address.

Dr. Jerry Segal commented that the proposal was very comprehensive and expressed concern about who will maintain the information in a data base. Dr. Hearn agreed that blinding is not possible; no institution can blind everything. He suggested focusing on the angiogram review, and if there is a question about appropriateness, then look at the patients' medical records.

Dr. Christopher Haas commented that the information in a patient's record is as important as what is on film; however, MHCC's proposal gets too far into the weeds. It needs to focus on whether a patient going to the cardiac catheterization laboratory is appropriate for PCI. He noted that documentation is easy to find if the appropriate use calculator is used. He also commented that the questions proposed by MHCC for the external review are more appropriate for retrospective review, if there is a concern. His hospital does a prospective review of appropriateness for cases using a tool developed by SCAI. He added that if everyone used the same tool, then it would be easy for an external reviewer. Dr. Hearn agreed.

Dr. Thomas commented that he believes all hospitals should be doing external review. His system was committed to external review before this happened, and he sees it as reasonable. However, he thinks it makes sense to have good screening that identifies hospitals and physicians that do things wrong. However, the proposed level of intensity for case reviews concerned him.

Dr. Aversano commented that "proposed" is the operative word, and MHCC staff confirmed that his understanding was correct. Ms. Fleck also noted that there seemed to be a lot of pushback on what staff has proposed. Dr. Aversano then suggested that members of the work group propose alternatives, noting that one had been mentioned by Dr. Haas, which entails making appropriate use calculations,

Dr. Mauro Moscucci noted that he agreed with other members comments. He also mentioned that in Michigan, during the 1990s, BlueCross BlueShield tried external review, but it abandoned it. He suggested an alternative approach would be random auditing of the National Cardiovascular Data registry (NCDR) which are used to calculate appropriate use. Dr. Aversano asked for clarification on Dr. Moscucci's proposal. He asked whether the proposal was to use five percent of the data in the NCDR database along with the angiograms for review. Dr. Moscucci explained that all hospitals would have to participate in the NCDR data registry, which MHCC staff noted is already required, and then use the data to see how hospitals' perform on appropriate use criteria and use a random audit by a state group similar to New York and Massachusetts, with angiographic review.

Dr. Haas commented that the pursuit of an external review process that is efficient and that has integrity is a noble one and that is what has been codified. He suggested that a way to make it easier is to use SCAI 's appropriate use calculator. He asked whether the State could mandate use of SCAI's calculator. At his hospital, he noted that for the past two years, every angiogram in every case has been reviewed; NCDRs evaluation of the appropriateness of cases went from 40% inappropriate to 10% inappropriate, after using the calculator. He noted that if the calculator labels a case as inappropriate, then a heart team approach is taken; a cardiac surgeon is consulted. He added that the approach is efficient and easy. He personally looks at all angiograms. It only takes a half hour of his time each week to review, although his hospital has only a small volume of cases.

Stephen Hearn noted that cardiac catheterization laboratory staff inputs a lot of the data, and there are cheat sheets all over the laboratory. Dr. Aversano noted that the key is auditing and Dr. Moscucchi agreed.

Mr. Steffen explained that the Maryland Chapter of the American College of Cardiology pushed the Maryland legislature for an external review requirement; the Commission did initiate the requirement. Commission staff is now soliciting input on developing more detailed standards for external review.

Dr. Seides commented that implicit in a requirement for external review is the assumption that if you have a bad actor at a hospital, then everyone in the hospital is in collusion with that bad actor; and he strongly disagrees with that assumption. He believes the process would be best served by looking at how hospitals approach internal review. All are participating in the NCDR database, and the need to send films out creates a level of complexity, cost, and resistance that no one wants.

Dr. Aversano commented that the NCDR database would have shown nothing was amiss at St. Joseph Hospital during the time period when Dr. Midei inappropriately performed PCI on patients who did not need it. Dr. Seides responded by clarifying that he is not suggesting that the NCDR database be the sole source for evaluating programs. He noted that at his institution films are reviewed for all physicians each year. He added that medical notes can be gamed too, as well as anything that is subjective, and institutions need to be regarded as the first line of review. Furthermore, he noted that the cost in time and dollars is astronomical, if cases are blinded and shipped around the State.

Dr. Aversano responded that Dr. Seides' ideas are noble, but the appearance of objectivity evaporates if reviews of cases are internal, by physicians analyzing the cases of their peers. Dr. Seides pointed out that internal review is acceptable for every other field, but cardiology. Dr. Aversano noted that the system catastrophically failed and that prompted the external review requirement.

Dr. David Zimrin asked for confirmation that the requirement of external review for five percent of PCI cases has been established by law. Ms. Fleck confirmed that Dr. Zimrin's understanding is correct. Dr. Zimrin added that Dr. Miller presented what Johns Hopkins Hospital and the University of Maryland Medical System are doing, which is reasonably low

cost, low input, and blinded review process. However, he thinks MHCC's staff proposal gets too much in the weeds and is unnecessary. His understanding is that the goal is to prevent a rogue operator. He proposed a process where films, cardiac catheterization laboratory report, and the admission note can be de-identified and sent to a common core, who then sends them out without knowing the origin according to AHA/ACC criteria and clinical appropriateness. He commented that the AHA/ACC criteria may be outdated due to the time required to develop new standards. He noted that the process requires central organization, but the reviews are relatively quick.

Mr. Josemartin Ilao commented that objectivity is important, and he agreed than an audit is important. He added that as someone who has been a patient and may be a patient again without the opportunity to choose which hospital in an emergency situation, he has a strong interest in the State audit system. He also suggested looking at New York as a model and trying to improve upon their system.

Dr. Stafford Warren commented that the Maryland Chapter of the American College of Cardiology was hoping that the model described by Dr. Zimrin will be adopted by all Maryland hospitals because it would accomplish the goal of external review and would be an educational opportunity for physicians participating in the review of cases. The intent was to make it something positive, not something punitive. He agreed with Dr. Zimrin's comments, and he added that with internal review, there is a potential for peers' biases to influence the outcomes of case review unfavorably.

Ms. Sharon Sanders commented that from an administrator's point of view, she agrees that there needs to be a level of quality and accountability, but keeping cost down is important too.

Mr. Steffen acknowledged that he understood the consensus of the group seemed to be that too many details were included in MHCC's staff proposal for external review. However, he suggested reviewing the proposal point-by-point, as planned to get additional feedback. Ms. Fleck agreed to proceed with a review of the MHCC staff proposal, but proposed skipping the discussion of whether MHCC should be approving organizations that conduct external reviews for Maryland Hospitals. No one objected.

Ms. Fleck stated that MHCC staff proposes that only board certified interventionalists who have practiced in the past five years should conduct reviews and asked for feedback on that proposed standard. Dr. Seides commented that there are many qualified interventionalists for reviews who may not be board certified or who let their board certification lapse. He described his position on the issue as neutral, but he noted that there is not universal acceptance of the importance of interventional cardiology boards for experienced interventionalists. Ms. Fleck commented that there could be some exceptions to the requirement adopted, and Mr. Steffen noted that the clinical advisory group had considered allowing non-board certified interventionalists in some situations. Mr. Steffen asked if anyone else wanted to comment. One member commented that it seemed reasonable, and Ms. Fleck asked if there was consensus on the issue. No one voiced dissent.

However, Dr. Aversano asked for clarification on the role of a nurse in reviewing some information in the records for a case. He wanted it be clear that nurses should not interpret information. Dr. Haas commented that facilities should make sure information has been properly collected before sending out for external review and other members agreed. Dr. Moscucci proposed having a standardized form for it. Other work group members agreed. Ms. Fleck asked if it should be standard among all hospitals and whether it would be difficult to develop. A member on phone commented that it would be helpful if data could come from an existing database.

Dr. Aversano asked if MHCC is getting NCDR data directly and whether hospitals could just strip off that data for cases that are reviewed. Ms. Fleck responded that she thinks it is a possibility and would be an efficient way to get quite a bit of the information needed, but some additional information may be needed.

Ms. Fleck asked if should there be training mandated for reviewers. Mr. Steffen inquired about the training for MACPAQ, an existing blinded system of case review used by the University of Maryland Medical System and Johns Hopkins Hospital. Dr. Zimrin responded that there are only four reviewers for MACPAQ, and it is developing training. He expects that is will be a straight-forward process. Ms. Fleck asked if anyone else wanted to comment.

Dr. Seides asked for clarification that the question to be answered is whether the patient was appropriate for PCI services. He noted that the need for training depends on the questions that are being asked. Ms. Fleck commented that many members of the group seemed to be proposing that the focus of the external review be only on appropriateness, but she had expected that it might be more than just evaluating appropriateness.

Dr. Haas commented that external review should only be an evaluation of appropriateness. He also expressed strong reservations about the State potentially infringing on the autonomy of physicians. He also noted that questioning a physician's judgment after the fact is very difficult because it is hard to know the physician's thinking process as the case unfolded. Dr. Zimrin agreed that the external review should only focus on appropriateness. Dr. Aversano asked whether it would be excessive for an external reviewer to say that a different course of action should have been considered. Dr. Haas did not think it would be excessive, but he again expressed concern about the State overreaching.

Dr. Segal commented that he thought both the appropriateness of the procedure and the appropriateness of the procedure that was done should be considered. He noted that everyone has probably seen cases where a 'full metal jacket' was used that was not needed.

Dr. Zimrin commented that MACPAQ evaluates quality, not just appropriateness, but in a limited way. It does not include how a procedure should have been done. If there is an obvious dissection that was not noted in record, then it will be noted by the reviewer. As a screening tool, he thinks that a detailed external review is not a good idea. He noted that the best way to get good outcomes is to do procedures that do not need to be done, and the idea to deter a rogue physician through the random selection of cases reviewed externally. He reiterated that quality is a side issue of appropriateness. Dr. Thomas agreed with Dr. Haas's concerns. Dr.

Aversano commented that if a case reviewed had a dissection at end of the case that was not noticed or treated and the patient dies, then a reviewer should be able to make a comment. Would the case be judged appropriate or not?

Dr. Seides responded that it was important to contain the scope of the external review requirement before it becomes a monster. He explained that quality has more to do with a pattern of care than an individual case. He does not think it should be within the purview of the reviewer. Instead, it should be handled by the physician's institution, and he also expressed confidence that the institutions that he is affiliated with would handle it appropriately.

Dr. Moscucchi commented that in the case of the dissection example given by Dr. Aversano, it would be reviewed through the internal peer review process. He also noted that in Michigan hospitals created a consortium for sharing data and working on quality improvement projects, which is also an option to consider.

Ms. Fleck suggested moving on to the next set of questions. She noted that patient selection criteria are in the regulations, and a reviewer should see if a physician followed guidelines for transfer and cardiogenic shock.

Dr. Haas asked Lisa Myers whether the proposed questions are redundant with a review by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) for its designation of hospitals as Cardiac Interventional Centers (CICs). Ms. Myers responded that ten STEMI cases were reviewed for each hospital, which were pulled from the NCDR ACTION database. Dr. Hass suggested that external review may not be needed for primary PCI cases. Dr. Aversano asked whether the ECG is reviewed. Ms. Myers responded that the reviewers look for a copy of the qualifying ECG, as well as other documentation. Dr. Aversano commented that it did seem redundant. Dr. Warren added that elective cases were the problem before. Ms. Fleck commented that she agreed that if there is already a process looking at those cases, then it would be fine to exclude from external review. Ms. Bruce commented that data could trigger a review too.

Ms. Fleck noted that they would move on to the discussion questions for the review of elective PCI cases. Ms. Fleck suggested that a reviewer should look at whether the patient was appropriate for elective PCI based on national guidelines referenced in MHCC's regulations and evaluate whether high risk patients treated at hospitals without cardiac surgery should have gone to a hospital with cardiac surgery on site.

Dr. Zimrin commented that asking whether the procedure is appropriate for a patient based on guidelines is fine and whether the procedure was appropriate. However, asking whether the patient should have been treated at a hospital with cardiac surgery on-site is not appropriate. He believes that if a procedure was inappropriately done at a hospital, then it will show up in the NCDR database. He also noted that the reviewer's judgment will be very subjective and expressed concern about creating a long review process.

Dr. Seides commented that it is often a matter of the operator's skill, not the institution. He added that everyone will agree that some procedures should not be done at a non-SOS hospital, but there is a broad grey area. He also reiterated that guidelines are just guidelines.

Ms. Fleck responded that staff understands that guidelines are only guidelines. With regard to Dr. Zimrin's comments, Ms. Fleck noted that she thought risk factors are not captured well in the NCDR database, so having a clinician review cases would be helpful. Dr. Zimrin responded that his point was that a physician who is doing cases that he should not be doing will have bad outcomes that show up in the NCDR data. Another member agreed with Dr. Zimrin's comments.

Mr. Ilao asked whether patients are informed about whether they meet the guidelines for elective PCI and whether the regulations should include such a requirement. Dr. Seides responded that informed consent is essential and documented in each patient's chart. Patients are told risks, benefits, and alternatives. He added that patients are usually shown videos or given booklets too. He did not think it would be helpful to tell a patient which guideline his or her case fits.

Dr. Segal commented that he thought patients presenting at hospitals without cardiac surgery on-site had to be informed of the risks of having the procedure performed in a hospital without surgery on-site. Ms. Fleck responded that after the C-PORT E follow-on study ended, MHCC suggested that hospitals continue to inform patients of the risks that he noted. However, it was left up to hospitals to decide how to handle it.

Ms. Fleck moved on to the third discussion question in this section, related to patients at high-procedural risk at non-SOS hospitals, and noted that it had been covered. She moved on to the fourth question, and asked for feedback. The two-part question was the following: If a lesion is 70% or less, then was FFR, IVUS, or a positive stress test used to confirm whether PCI is appropriate? Alternatively, was there documentation that supported the conclusion that these tests would be contraindicated?

Dr. Haas commented that it is included in the SCAI calculator and implicit in the guidelines. Dr. Hearn agreed with Dr. Haas. Dr. Haas added that it is fine to explicitly include the question, but it should not be necessary.

Ms. Fleck asked if there were any additional questions for this section that should be included on the list. Dr. Aversano commented that a question about medication should be included. Dr. Haas further explained that appropriateness depends on angina class, medications, past history of bypass surgery, and results of stress test. Those are the key factors to consider for the SCAI calculator. He offered to provide a link.

Ms. Fleck moved on to the next set of discussion questions, at the bottom of page 5 of the discussion guide. The group agreed that the first question was fine. For the second question, regarding documentation of patient consent, it was noted that the Joint Commission checks for it, when it reviews a hospital. Members agreed that it was unnecessary to include in the requirements for external review. Ms. Fleck moved on to the question pertaining to renal failure,

and asked the workgroup about including it. Dr. Haas responded that he felt it was more appropriate to retrospectively look at it, if a hospital has a high number of cases with patients experiencing renal failure. Dr. Moscucci agreed that the question should not be included.

Ms. Fleck moved on to the next set of questions on page six of the discussion guide. Dr. Zimrin commented that several of the questions are used at St. Joseph Medical Center for its internal review, but he did not think the questions were appropriate for external review. The work group agreed that the set of five questions in this section is excessive.

Dr. Thomas commented that external reviewers come up with their own questions specific to the case being reviewed; external reviewers do not have to be scripted. Ms. Fleck responded that she is trying to ensure that reviewers are consistent in how they handle cases. Dr. Thomas commented that screening to find bad actors or institutions is fine, but he fears going too far. He added that there are a lot of helpful databases, and a more rigorous approach to internal peer review than in previous years.

Dr. Aversano commented that there were two levels of review discussed by the clinical advisory group that informed the development of new regulations. He agreed that the questions seemed more for a red flag review than a screening type of review. Ms. Fleck noted that she understood the consensus of the group and moved on to the next set of questions at the bottom of page six. She read the first question regarding the appropriate time frame for evaluating adverse patient outcomes. Dr. Aversano indicated that he thought the information was available in summary form from the NCDR database. Ms. Fleck responded that Dr. Aversano is correct, but she thought an external reviewer would be more qualified to make judgments about what complications are concerning. Dr. Zimrin commented that internal review covers cases with adverse outcomes. Other members of the group, including Dr. Aversano, Dr. Haas, Dr. Hearne, Dr. Moscucci, and Dr. Segal indicated that reviewing the NCDR data should be sufficient, and the external review should just be a screening tool.

Ms. Fleck moved on to the next set of questions on page seven of the discussion guide that cover the review of angiographic images. She read all three questions and asked for feedback on the questions. Dr. Seides responded that the third question is appropriate. In his view, the other two questions are subjective and not germane. Dr. Haas commented that the third question incorporates the first two questions, and some other members agreed. Ms. Fleck asked if there were other questions that should be added. No one suggested any additional questions.

Ms. Fleck moved on to the next set of questions that pertain to the physician's actions post-procedure. Dr. Segal commented that an extensive chart review would be needed to cover the questions. Dr. Haas commented that complications linked only to the angiographic image review is reasonable, but not complications broadly. Ms. Fleck asked if anyone else had comments. Dr. Hearne asked about the timeframe for the second question. Several members recommended focusing on only the procedure.

Dr. Haas commented that there are other sources that may be used to identify complications, and it should be picked up later by other hospital staff, even if the physician fails to note it in the cardiac catheterization report.

Ms. Fleck moved on to the next set of questions on page eight of the discussion guide, which pertain to recommendations from an external reviewer. Mr. Ilao commented that he was concerned about having a questionable category for cases is problematic and would lead to the need for additional review. Dr. Seides commented that using only binary categories does not work. There are interventions that are only rarely appropriate, and he noted that the American College of Cardiology changed the categories to allow for clinical judgment.

Ms. Fleck asked whether a reviewer should recommend corrective actions or additional investigation. Dr. Thomas responded that it would not be appropriate, and some other members of the group strongly agreed. He noted that such an approach would strike fear in physicians. Dr. Segal commented that once an external reviewer identifies an issue, then internal review should be triggered. Dr. Haas commented that MHCC could have a process in place for reviewing a hospital's corrective action plan, but the external reviewer should not be involved. Dr. Aversano asked if a reviewer that has a concern could comment on that concern. Ms. Fleck asked if instead the reviewer should note that additional investigation is needed. Dr. Haas responded that the reviewer should state what was inappropriate, and then it is up to MHCC to determine what to do. He suggested having a panel of physicians review the case at that point. Dr. Aversano commented that the proposed approach sounded reasonable.

Dr. Hearne asked about whether the results of the review would be protected as confidential and part of the peer review process. Another member noted that despite the limited scope of the external review discussed, there could still be information that is fodder for a lawsuit. Mr. Steffen responded that he would like to investigate further and get back to the group.

Ms. Fleck asked the workgroup members if they wanted to continue with the agenda or end the meeting close to on-time. Mr. Steffen suggested deferring the discussion of the schedule of ongoing performance measurement. Instead, he suggested discussing nominations for a vice-chair. He suggested that people contact Ms. Fleck if they wanted to volunteer, and staff would have the Commission approve nominees. Mr. Steffen explained that he thought having co-vice chairs may be a good idea. Ms. Fleck noted that the number of meetings might be four times a year, but it would depend partly on the needs of the group. Dr. Seides suggested that Ms. Fleck email everyone a reminder about nominations. Mr. Steffen commented that he did not expect the role to be an onerous one. Mr. Steffen suggested finding out more about MAQPAC's review of cases, and Ms. Fleck said that she would follow-up with Dr. Miller. Mr. Steffen then closed the meeting.